

HFA-305
JUL 10

Neomycin 325 Soluble Powder®

FREEDOM OF INFORMATION SUMMARY

ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-050

Neomycin 325 Soluble Powder® (neomycin sulfate) 3.5 oz (100 g) and
50 lb (22.7 kg) packages

For treatment and control of colibacillosis (bacterial enteritis) caused by *Escherichia coli* susceptible to neomycin sulfate in cattle, swine, sheep, and goats.

For the control of mortality associated with *Escherichia coli* organisms susceptible to neomycin sulfate in growing turkeys.

Sponsored by:

Bimeda, Inc.

ANADA 200-050

FOIS-1

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION:

ANADA	200-050
Sponsor:	Bimeda, Inc. 291 Forest Prairie Road Le Sueur, Minnesota 56058
Generic Name:	neomycin sulfate
Trade Name:	Neomycin 325 Soluble Powder
Marketing Status:	Over The Counter
Supplemental Effect:	To provide for turkeys as an additional approved species based upon approval of turkeys in the pioneer product, and expiration of exclusivity period.
Pioneer:	Pharmacia and Upjohn Company/Neomix® 325 NADA 11-315

II. INDICATIONS FOR USE:	For the treatment and control of colibacillosis (bacterial enteritis) caused by <i>Escherichia coli</i> susceptible to neomycin sulfate in cattle, swine, sheep, and goats. For the control of mortality associated with <i>Escherichia coli</i> organisms susceptible to neomycin sulfate in growing turkeys.
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III. DOSAGE:

A. Dosage Form:	Soluble Powder
B. How Supplied:	3.5 oz (100 g) and 50 lb (22.7 kg) packages
C. Amount of Active Ingredient:	Neomycin sulfate soluble powder contains 20.3 grams of neomycin sulfate (equivalent to 14.2 grams of neomycin base) per ounce.
D. Route of Administration	Orally in drinking water (turkeys) or milk and water (other species).
E. Species:	Cattle (excluding veal calves), Swine, Sheep, Turkeys

(new), and Goats.

F. Labeled Dosage:

Cattle, Swine, Sheep, and Goats - 10 mg/lb body weight daily in divided doses for a maximum of 14 days.

Growing Turkeys – 10 mg/lb body weight daily for a maximum of 5 days.

IV. TARGET ANIMAL SAFETY AND DRUG EFFECTIVENESS:

Under the provisions of the Federal Food, Drug and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act, (53 FR 50460, December 15, 1988, First GADPTRA Policy Letter) an abbreviated new animal drug application (ANADA) may be submitted for a generic version of an approved new animal drug (pioneer product). Drug effectiveness data, and human food safety data (other than tissue residue data) are not required for approval of an ANADA. An ANADA relies on the target animal safety, drug effectiveness, and human food safety data in the pioneer's new animal drug application. Ordinarily, the ANADA sponsor shows that the generic product is bioequivalent to the pioneer. If bioequivalence is demonstrated through a clinical end-point study, then a tissue residue study to establish the withdrawal time for the generic product is also required. For certain dosage forms, the agency will grant a waiver from conducting an *in vivo* bioequivalence study (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 2000).

Based upon the formulation characteristics of the generic product, the sponsor was granted a waiver from conducting an *in vivo* bioequivalence study for neomycin sulfate soluble powder. The generic product is administered as an oral solution and contains the same active ingredient and drug concentration as the pioneer and contains no inactive ingredients that may significantly affect the absorption of the active ingredient.

The basis for this supplemental ANADA approval was published in 64 FR 31498, June 11, 1999, and provided for the use of neomycin sulfate in turkey drinking water for the control of mortality claim.

V. HUMAN FOOD SAFETY:

Tolerances:

The tolerances established for the pioneer product apply to the generic product. Neomycin residues in the uncooked edible tissues of cattle, swine sheep, goats and turkeys as published in 21 CFR 556.430 are:

7.2 parts per million (ppm) in kidney (target tissue) and fat, 3.6 ppm in liver, and 1.2 ppm in muscle of cattle (except veal calves), swine, sheep, and goats and a tolerance of 0.15 ppm is established in milk.

7.2 parts per million (ppm) in skin with adhering fat, 3.6 ppm in liver, and 1.2 ppm in muscle of turkeys.

Withdrawal Times (21 CFR 520.1484):

Cattle (excluding veal calves)	1 Day
Swine	3 Days
Goats	3 Days
Sheep	2 Days
Turkeys	0 Days

Regulatory Method for Residues:

The regulatory analytical method for detection of residues of the drug is a microbiological test using *Staphylococcus epidermidis* suspension. The method is published by the Food and Drug Administration, "Antibiotic Residues in Milk, Dairy Products and Animal Tissues: Methods, Reports, and Protocols", revised October 1968, reprinted December 1974. The method is available from the Food and Drug Administration, Center for Veterinary Medicine, 7500 Standish Place, Rockville Maryland 20855.

VI. AGENCY CONCLUSIONS:

This ANADA submitted under section 512(b) of the Federal Food, Drug, and Cosmetic Act satisfies the requirements of section 512(n) of the act and demonstrates that Neomycin 325 Soluble Powder when used under its proposed conditions of use, is safe and effective for its labeled indications.

Final Product Labeling [100 gram pouch and 50 pound drum] and currently approved Pioneer labeling [100 gram pouch and a copy of the Compendia for Veterinary Products, 2001, reflecting labeling for the 50 pound drum] are attached:

cc: Courtesy copy for the sponsor
HFV-199, NADA Orig. [white copy]
HFV-2, Special Mailing List
HFV-12 FOI Staff
HFV-102, Reserve Copy
HFV-102, Greenbook
HFV-120, Labeling Project
HFA-305, Dockets Management Branch
HFR-CE850, Minnesota District Office Copy

NEOMYCIN 325 Soluble Powder

Neomycin Sulfate (commercial grade)

Antibacterial

For the treatment and control of colibacillosis (bacterial enteritis) caused by *Escherichia coli* susceptible to neomycin sulfate in cattle (excluding veal calves),

swine, sheep, and goats.

For the control of mortality associated with *Escherichia coli* organisms

susceptible to neomycin sulfate in growing turkeys.

Each Pound Contains: 325 g neomycin sulfate (commercial grade) equivalent to

FOR ANIMAL USE ONLY

NOT FOR HUMAN USE

KEEP OUT OF REACH OF CHILDREN

ANADA 200-050, Approved by FDA

NET CONTENTS: 50 Pounds (22.7 kg)



Bimeda

Lot
Exp:



The product should be added to the amount of drinking water estimated to be consumed in 12-24 hours. Provide medicated water as the sole source of water each day until consumed, followed by non-medicated water as required. Fresh medicated water should be prepared each day. For a stock solution, add six level tablespoons to one gallon of water. Each pint of this stock solution will medicate 5 gallons of drinking water. For use in automatic proportioners delivering 2 ounces of stock solution per gallon of drinking water, dissolve 8 level tablespoons in a gallon of water to make the stock solution.

Individual Animal Treatment: To provide 10 mg neomycin sulfate per pound of body weight, mix one (1) level teaspoon in water or milk for each 160 pounds of body weight. Administer daily either as a drench in divided doses or in the drinking water to be consumed in 12-24 hours.

Caution(s): To administer the stated dosage, the concentration of neomycin required in medicated water must be adjusted to compensate for variation in age and weight of animal, the nature and severity of disease signs, and environmental temperature and humidity, each of which affects water consumption.

If symptoms persist after using this preparation for 2 or 3 days, consult a veterinarian. If symptoms such as fever, depression or going off feed develop, oral neomycin is not indicated as the sole treatment since systemic levels of neomycin are not obtained due to low absorption from the gastrointestinal tract.

Important: Treatment should continue 24 to 48 hours beyond the remission of disease symptoms, but not to exceed a total of 14 consecutive days for cattle, swine, sheep and goats and 5 days for turkeys. Animals not drinking or eating should be treated individually by drench.

Warnings: Discontinue treatment prior to slaughter by at least the number of days listed below for appropriate species:

Cattle	1 day
Swine and goats	3 days
Sheep	2 days
Turkeys	0 days

A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

A milk discard period has not been established for this product in lactating dairy cattle. Do not use in female dairy cattle 20 months of age or older.

For oral use in animals only.
Add to drinking water - Not for use in liquid supplements
Dosage and Administration: Administer to cattle (excluding veal calves), swine, sheep and goats at a dose of 10 mg of neomycin sulfate per pound of body weight per day in divided doses for a maximum of 14 days. Administer to turkeys at a dose of 10 mg neomycin sulfate per pound of body weight per day in for 5 days. Using measuring spoons, the recommended dosage can be determined as follows:

Daily Schedule for Drinking Water:

Swine:

One tablespoonful of NEOMYCIN 325 added to water consumed in one day will treat:	Weight of each pig
50 pigs	10 pounds
20 pigs	25 pounds
10 pigs	50 pounds

Cattle

One tablespoonful of NEOMYCIN 325 added to water or milk consumed in one day will treat:	Weight of each calf
10 calves	50 pounds
7 calves	75 pounds
4 calves	125 pounds

Turkeys:

One tablespoonful of NEOMYCIN 325 added to water or milk consumed in one day will treat:	Weight of each bird
1000 birds	0.5 pounds
500 birds	1 pound
100 birds	5 pounds
50 birds	10 pounds

*Level Tablespoonful = US Standard Measure

When storing partially used containers, securely close bags and keep container tightly closed to prevent contents from caking. Store at controlled room temperature. Restricted Drug - Use Only As Directed (California).

Product No. 1NE0007

8NE0003-1201

Manufactured By:

Bimeda, Inc.

Le Sueur, MN 56058



8NE0003-1201 100% SIZE 6" X 10" PRINTS BLACK PMS 179

DEC 19 2001

NDC 0009-0553-05

Neomix[®] 325

Soluble Powder

neomycin sulfate
(commercial grade)

Antibacterial



TM



TAKE TIME

OBSERVE LABEL
DIRECTIONS

For the control of mortality associated with *Escherichia coli* organisms susceptible to neomycin sulfate in growing turkeys. Contains per pound: 325 gms neomycin sulfate equivalent to 227.5 gm neomycin. NADA 141-376 Approved by FDA. Restricted Drug—Use Only as Directed (California).

Pharmacia
& Upjohn
NET WT
50 LB (22.6 Kg)

For Use in Animals Only — Keep Container Tightly Closed — Store at Room Temperature
Add to drinking water.—Not for use in liquid supplements
Dosage and Administration: Administer to turkeys at a dose of 10 mg neomycin sulfate per pound of body weight per day for 5 days. Administer to cattle, swine, sheep and goats at a dose of 10 mg neomycin sulfate per pound of body weight per day in divided doses for a maximum of 14 days. Using measuring spoons, the recommended dosage can be determined as follows:

Daily Schedule for Drinking Water

Swine		Cattle		Turkey	
One tablespoonful* of NEOMIX 325 added to water consumed in one day will treat	Weight of each pig	One tablespoonful* of NEOMIX 325 added to water or milk consumed in one day will treat	Weight of each calf	One tablespoonful* of NEOMIX 325 added to water consumed in one day will treat	Weight of each bird
50 pigs	10 pounds	10 calves	50 pounds	1000 birds	.5 pound
20 pigs	25 pounds	7 calves	75 pounds	500 birds	1 pound
10 pigs	50 pounds	4 calves	125 pounds	100 birds	5 pounds
				50 birds	10 pounds

*Level Tablespoonful = US Standard Measure

The product should be added to the amount of drinking water estimated to be consumed in 12-24 hours. Provide medicated water as the sole source of water each day until consumed, followed by non-medicated water as required. Fresh medicated water should be prepared each day. For a **Stock Solution**, add six level tablespoons to one gallon of water. Each pint of this stock solution will medicate 5 gallons of drinking water.

For use in **Automatic Proportioners** delivering 2 ounces of stock solution per gallon of drinking water, dissolve 9 level tablespoons in a gallon of water to make the stock solution. **Individual Animal Treatment**—To provide 10 mg neomycin sulfate per pound of body weight, mix one (1) level teaspoon in water or milk for each 160 pounds of body weight. Administer daily either as a drench in divided doses or in the drinking water to be consumed in 12-24 hours.

Caution: To administer the stated dosage, the concentration of neomycin required in medicated water must be adjusted to compensate for variation in age and weight of animal, the nature and severity of disease signs, and environmental temperature and humidity, each of which affects water consumption. If symptoms persist after using this preparation for 2 or 3 days, consult a veterinarian. If symptoms such as fever, depression or going off feed develop, oral neomycin is not indicated as the sole treatment since systemic levels of neomycin are not obtained due to low absorption from the gastrointestinal tract.

Important: Treatment should continue 24 to 48 hours beyond remission of disease symptoms, but not to exceed a total of 14 consecutive days for cattle, swine, sheep, goats, and 5 days for turkeys. Animals not drinking or eating should be treated individually by drench.

Warning: Not for human use. Keep out of reach of children. Discontinue treatment prior to slaughter by at least the number of days listed below for the appropriate species:

- Turkeys 0 days
 - Cattle 1 day
 - Swine 2 days
 - Sheep and goats 3 days
- A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. A milk discard period has not been established for this product in lactating dairy cattle. Do not use in female dairy cattle 20 months of age or older.

Important: Store in a dry place. When storing partially used containers, securely close bags to prevent contents from caking.

NET WT 50 LB

3 0009-0553-05 0

PURCHASE SEAL

813 288 208

Pharmacia & Upjohn Company
Kalamazoo, MI 49001, USA

NEOMYCIN 325

Soluble Powder

Neomycin Sulfate (commercial grade)

Antibacterial

For the treatment and control of colibacillosis (bacterial enteritis) caused by *Escherichia coli* susceptible to neomycin sulfate in cattle (excluding veal calves), swine, sheep and goats. For the control of mortality associated with *Escherichia coli* organisms susceptible to neomycin sulfate in growing turkeys.

EACH PACKET CONTAINS: 71.4 g neomycin sulfate (commercial grade) equivalent to 50 g neomycin.

FOR ANIMAL USE ONLY
NOT FOR HUMAN USE
KEEP OUT OF REACH OF CHILDREN

ANADA 200-050, Approved by FDA

NET CONTENTS: 100 Grams (3.5 Oz)

Restricted Drug - Use Only As Directed (California)

Product No. 1NE0002
8NE0002-102

TAKE TIME

OBSERVE LABEL
DIRECTIONS

Manufactured by
Bimeda, Inc.
Le Sueur, MN 56058

Osborn®



NEOMYCIN 325

Add to drinking water - Not for use in liquid supplements.

DOSAGE AND ADMINISTRATION: Administer to cattle (excluding veal calves), swine, sheep and goats at a dose of 10 mg neomycin sulfate per pound of body weight per day in divided doses for a maximum of 14 days. Administer to turkeys at a dose of 10 mg neomycin sulfate per pound of body weight per day for 5 days.

Herd/Flock Treatment: Each packet will treat 7150 pounds of body weight. Therefore, estimate the total number of pounds of body weight of the animals to be treated and administer one (1) packet (or portion thereof) for each 7150 pounds. The product should be added to the amount of drinking water estimated to be consumed in 12-24 hours. Provide medicated water as the sole source of water each day until consumed, followed by non-medicated water as required. Fresh medicated water should be prepared each day.

Individual Animal Treatment: To provide 10 mg neomycin sulfate per pound of body weight, mix one (1) level teaspoon in water or milk for each 160 pounds body weight. Administer daily either as a drench in divided doses or in the drinking water to be consumed in 12-24 hours.

Drinking Water: Swine - Use the number of packets indicated below in 256 gallons of water, or in two gallons of stock solution used in proportioner set to meter one ounce per gallon.

Pigs Weighing 25 to 50 Pounds..	2 Packets
Pigs Weighing 50 to 100 Pounds..	3 Packets
Pigs Weighing Over 100 Pounds..	4 Packets

CAUTION: To administer the stated dosage, the concentration of neomycin required in medicated water must be adjusted to compensate for variation in age and weight of animal, the nature and severity of disease signs, and environmental temperature and humidity, each of which affects water consumption.

If symptoms persist after using this preparation for 2 or 3 days, consult a veterinarian. If symptoms such as fever, depression, or going off feed develop, oral neomycin is not indicated as the sole treatment since systemic levels of neomycin are not obtained due to low absorption from the gastrointestinal tract.

IMPORTANT: Treatment should continue 24 to 48 hours beyond remission of disease symptoms, but not to exceed a total of 14 consecutive days for cattle, swine, sheep and goats and 5 days for turkeys. Animals not drinking or eating should be treated individually by drench.

WARNING: Discontinue treatment prior to slaughter by at least the number of days listed below for appropriate species.

Cattle..	1 day
Swine and goats ..	3 days
Sheep ..	2 days
Turkeys ..	0 days

A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

A milk discard period has not been established for this product in lactating dairy cattle. Do not use in female dairy cattle 20 months of age or older.

Fold opened packet tightly to keep out moisture.

Store at controlled room temperature.

NET CONTENTS: 100 Grams (3.5 Oz)

Manufactured by
Bimeda, Inc.
Le Sueur, MN 56058

NDC 0009-0553-40

Neomix® 325

Soluble Powder

neomycin sulfate (commercial grade)

Antibacterial



For Use in Animals Only

Store at room temperature

Add to drinking water—Not for use in liquid supplements

Dosage and Administration: Administer to turkeys at a dose of 10 mg neomycin sulfate per pound of body weight per day for 5 days. Administer to cattle, swine, sheep and goats at a dose of 10 mg neomycin sulfate per pound of body weight per day in divided doses for a maximum of 14 days.

Herd/Flock Treatment: Each packet will treat 7150 pounds body weight. Therefore, estimate the total number of pounds of body weight of the animals to be treated and administer one (1) packet (or portion thereof) for each 7150 pounds. The product should be added to the amount of drinking water estimated to be consumed in 12-24 hours. Provide medicated water as the sole source of water each day until consumed, followed by non-medicated water as required. Fresh medicated water should be prepared each day.

Individual Animal Treatment: To provide 10 mg neomycin sulfate per pound of body weight, mix one (1) level teaspoon in water or milk for each 160 pounds body weight. Administer daily either as a drench in divided doses or in the drinking water to be consumed in 12-24 hours.

Drinking Water: Use the number of packets indicated below in 256 gallons of water, or in two gallons of stock solution used in proportioners set to meter one ounce per gallon.

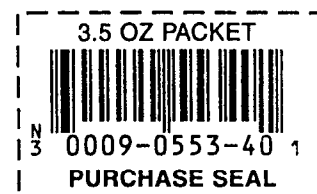
Swine:

Pigs Weighing 25 to 50 Pounds 2 Packets
Pigs Weighing 50 to 100 Pounds 3 Packets
Pigs Weighing Over 100 Pounds 4 Packets

Caution: To administer the stated dosage, the concentration of neomycin required in medicated water must be adjusted to compensate for variation in age and weight of animal, the nature and severity of disease signs, and environmental temperature and humidity, each of which affects water consumption.

If symptoms persist after using this preparation for 2 or 3 days, consult a veterinarian. If symptoms such as fever, depression, or going off feed develop, oral neomycin is not indicated as the sole treatment since systemic levels of neomycin are not obtained due to low absorption from the gastrointestinal tract.

Important: Treatment should continue 24 to 48 hours beyond remission of disease symptoms, but not to exceed a total of 14 consecutive days for cattle, swine, sheep, goats, and 5 days for turkeys. Animals not drinking or eating should be treated individually by drench.



Pharmacia & Upjohn Company
Kalamazoo, MI 49001, USA

Warning: Not for human use. Keep out of reach of children. Discontinue treatment prior to slaughter by at least the number of days listed below for the appropriate species:

Turkeys0 days
Cattle1 day
Sheep2 days
Swine and goats3 days

A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. A milk discard period has not been established for this product in lactating dairy cattle. Do not use in female dairy cattle 20 months of age or older.

NEOMYCIN 325 Soluble Powder

Neomycin Sulfate (commercial grade) Antibacterial

For the treatment and control of colibacillosis (bacterial enteritis) caused by *Escherichia coli* susceptible to neomycin sulfate in cattle (excluding veal calves), swine, sheep, and goats.

For the control of mortality associated with *Escherichia coli* organisms susceptible to neomycin sulfate in growing turkeys.

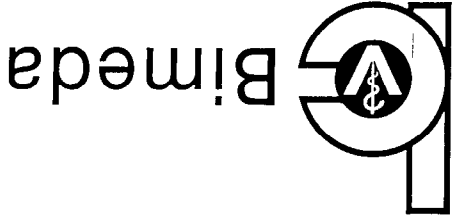
Each Pound Contains: 325 g neomycin sulfate (commercial grade) equivalent to 277.5 g neomycin.

FOR ANIMAL USE ONLY NOT FOR HUMAN USE

KEEP OUT OF REACH OF CHILDREN

ANADA 200-050, Approved by FDA

NET CONTENTS: 50 Pounds (22.7 kg)



Lot:
Exp:



The product should be added to the amount of drinking water estimated to be consumed in 12-24 hours. Provide medicated water as the sole source of water each day until consumed, followed by non-medicated water as required. Fresh medicated water should be prepared each day. For a stock solution, add six level tablespoons to one gallon of water. Each pint of this stock solution will medicate 5 gallons of drinking water. For use in automatic proportioners delivering 2 ounces of stock solution per gallon of drinking water, dissolve 9 level tablespoons in a gallon of water to make the stock solution.

Individual Animal Treatment: To provide 10 mg neomycin sulfate per pound of body weight, mix one (1) level teaspoon in water or milk for each 160 pounds of body weight. Administer daily either as a drench in divided doses or in the drinking water to be consumed in 12-24 hours.

Cautions(s): To administer the stated dosage, the concentration of neomycin required in medicated water must be adjusted to compensate for variation in age and weight of animal, the nature and severity of disease signs, and environmental temperature and humidity, each of which affects water consumption.

If symptoms persist after using this preparation for 2 or 3 days, consult a veterinarian. If symptoms such as fever, depression or going off feed develop, oral neomycin is not indicated as the sole treatment since systemic levels of neomycin are not obtained due to low absorption from the gastrointestinal tract.

Important: Treatment should continue 24 to 48 hours beyond the remission of disease symptoms, but not to exceed a total of 14 consecutive days for cattle, swine, sheep and goats and 5 days for turkeys. Animals not drinking or eating should be treated individually by drench.

Warnings(s): Discontinue treatment prior to slaughter by at least the number of days listed below for appropriate species:

Cattle: 1 day
Swine and goats: 3 days
Sheep: 2 days
Turkeys: 0 days

A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

A milk discard period has not been established for this product in lactating dairy cattle. Do not use in female dairy cattle 20 months of age or older.

For oral use in animals only.

Add to drinking water - Not for use in liquid supplements.

Dosage and Administration: Administer to cattle (excluding veal calves), swine, sheep and goats at a dose of 10 mg of neomycin sulfate per pound of body weight per day in divided doses for a maximum of 14 days. Administer to turkeys at a dose of 10 mg neomycin sulfate per pound of body weight per day in 5 days. Using measuring spoons, the recommended dosage can be determined as follows:

Daily Schedule for Drinking Water:

Swine:

One tablespoonful* of NEOMYCIN 325 added to water	consumed in one day will treat
Weight of each pig	50 pigs
10 pounds	25 pigs
50 pounds	10 pigs

Cattle:

One tablespoonful* of NEOMYCIN 325 added to water	or milk consumed in one day will treat
Weight of each calf	10 calves
50 pounds	7 calves
125 pounds	4 calves

Turkeys:

One tablespoonful* of NEOMYCIN 325 added to water	or milk consumed in one day will treat
Weight of each bird	1000 birds
0.5 pounds	500 birds
1 pound	100 birds
5 pounds	50 birds
10 pounds	50 birds

*Level Tablespoonful = US Standard Measure

When storing partially used containers, securely close bags and keep container tightly closed to prevent contents from caking. Store at controlled room temperature.

Restricted Drug - Use Only As Directed (California).

Product No. 1NE0007
8NE0003-1201
Manufactured By:
Bimeda, Inc.
Le Sueur, MN 56058

